Original article

Long-term survivorship of the Corail™ standard stem

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A R T I C L E   I N F O

Article history:
Received 23 January 2017
Accepted 19 June 2017

Keywords:
Primary THA
Cementless stem
Aseptic loosening
Corail
Long-term survival

A B S T R A C T

Introduction: The Corail™ stem, which was first introduced in 1986, has since been modified twice: first to make the neck thinner and then to change the location of the laser markings. The survival and complications of the first-generation straight, titanium, hydroxyapatite-coated stem are known; however, there is little specific information about the latest-generation stem. This led us to conduct a retrospective study to determine the: (1) long-term survival; (2) clinical and radiographic outcomes; (3) complications; and (4) risk factors for revision of the newest Corail™ stem.

Hypothesis: The newest Corail™ AMT (Articul/EZ™ Mini Taper) standard stem has comparable survival to prior models.

Patients and methods: This single-center, retrospective study included 133 patients (140 hips), who underwent primary total hip arthroplasty (THA), between January and December 2004, in which a Corail™ Standard stem was implanted using a posterolateral approach. Patients who underwent revision THA, THA due to femoral neck fracture or who received lateralized (offset) stems were excluded. The mean age at the time of THA was 69 ± 13 years (35–92) in 85 men (61%) and 55 women (39%) who had a mean BMI of 27 kg/m² ± 11 [16–39]. At the latest follow-up, 32 patients (32 hips) had died and 8 patients (8 hips) had less than 3 years’ follow-up, thus were not included in the clinical evaluation. The Merle d’Aubigné (PMA) score was collected. The stem’s survivorship was calculated using the Kaplan-Meier method with revision for aseptic loosening and revision or implant removal for any reason as the end-points. The Cox model was used to analyze risk factors for revision. The mean follow-up was 10 ± 3 years [3–12].

Results: The PMA score was 12 ± 2.6 [5–17] preoperatively and 16 ± 2.7 [7–18] at the last follow-up (P < 0.0001). Eighteen complications (12.8%) were recorded at the last follow-up. There were 15 early complications: 6 dislocations, 5 calcar fractures (4 treated by wire cerclage and 1 by stem change plus wire cerclage), 2 greater trochanter fractures (treated non-surgically) and 2 cases of sciatic nerve palsy. There were 3 late complications: 2 cases of iliopsoas irritation and 1 ceramic insert fracture. Stem survival for surgical revision due to aseptic loosening was 98% (95% CI: [0.96–1]). At 12 years, 95% of stems had not been revised or removed (95% CI: [0.92–0.991]). Being less than 58 years of age at the time of surgery was the only risk factor significantly associated with stem revision for any reason (P = 0.04).

Conclusion: Survival of the Corail™ Standard stem is similar to that of previous generation stems. The changes made in this stem solved the neck failure problem and did not induce new complications.

Level of evidence: Level IV (retrospective study).

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1. Introduction

The Corail™ stem (DePuySynthes, Warsaw, IN) – designed by the ARTRO group – has been in commercial use since 1986. This titanium, hydroxyapatite-coated stem is considered the gold standard of rectangular stems because of its excellent clinical outcomes [1]. This stem has been modified twice since it was first introduced. In the early 2000s, the neck was thinned and changed from a circular shape to a cylindrical-trapezoid design to reduce

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http://dx.doi.org/10.1016/j.otsr.2017.06.010
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impingement with the articular surface of the cup, thus improving range of motion and reducing wear. In the initial stem design, the stem’s name and lot number was laser etched on the neck, which resulted in a high failure rate due to thinning of the neck [2]. In December 2003, the laser etching was moved to the distal portion of the Morse taper resulting in the design (AMT–Articul/EZE™ Mini Taper) that is now used.

Several studies have evaluated the short, medium and long-term outcomes of the first generation Corail™ stem. Vidalain [1,3,4] evaluated the initial cohort of 2956 first-generation stems and found a 99% survivorship at 5 years, 98% at 10 years and 96% at 23 years of follow-up. At the last follow-up, more than half the patients had died and revisions were mainly performed for complications related to the cup (13 revisions for recurring dislocation and 62 bipolar revisions due to acetabular loosening). Only four stems had to be revised due to femoral loosening and one due to periprosthetic fracture. Merini et al. [2] looked at second-generation stems after 10 years’ follow-up. While only 267 of 295 stems (90.5%) were still in place, the stem fracture rate was 5.4% (16/295) (laser neck etching) and there was no aseptic loosening. Jameson et al. [5] found that using a small-sized stem (<11) in patients with a body mass index (BMI) > 30 kg/m² were risk factors for stem revision. There was no statistical relationship between other stem features (collar, offset) or head features (size, material), patient age, and sex with the risk of revision. Given the inconsistent results and the lack of studies on the latest-generation stem, we decided to determine the survival of the current Corail™ standard stem.

This led us to conduct a retrospective study to determine the:

• long-term survival;
• clinical and radiographic outcomes;
• complications;
• risk factors for revision of the current Corail™ standard stem.

We hypothesized that the newest Corail™ stem solves some of the complications associated with the second-generation stem without inducing new complications, and improves the survival.

2. Patients and methods

2.1. Patients

This single-center, retrospective study included 133 consecutive patients (140 hips) who underwent primary total hip arthroplasty (THA) between January and December 2004 during which a Corail™ standard stem (DepuySynthes, Warsaw, IN) was implanted by one of the surgeons in our department. During this inclusion period, 28 CorailKHO (high offset) stems, 26 CorailKLA (lateralized) stems, 4 all-collared stems, 3 dysplasia stems (Corail size 6) and 1 custom stem were implanted but not included in this study. Patients were included if they had undergone primary THA with a Corail™ standard stem. Exclusion criteria are summarized in Fig. 1. The main reasons for exclusion were implantation of a lateralized stem and patients who had less than 3 years’ follow-up (n = 3), which corresponds to the median revision time. Thirty-two patients (32 hips, 23%) had died after a mean of 7 ± 2 years (3–12) without undergoing revision. The average follow-up was 10 ± 2 years [3–12]. Demographic data are given in Table 1.

3. Methods

Either collared (KA, n = 112) or collarless (KS, n = 28) Corail™ standard stems were used, depending on the surgeon’s preferences (Fig. 2). The Corail™ standard stem is a straight rectangular stem made of titanium alloy (Ti6Al4V) that is flared out in the sagittal and frontal planes and coated with a 150-µm thick layer of hydroxyapatite. It has a 135° neck–shaft angle and proportionately scaled lateralization of 38 mm (size 8) to 46 mm (size 20). Preoperative planning was performed using templates over A/P pelvis radiographs with known magnification. The type of stem was determined during the planning steps.

The surgery was carried out on side-lying patients through a posterior approach under general anesthesia (116 cases, 83%) or spinal anesthesia (24 cases, 17%). One patient underwent

Fig. 1. Flowchart summarizing the inclusions and exclusions in this study.

Table 1. Demographics of the study cohort.

<table>
<thead>
<tr>
<th>Number of patients (hips)</th>
<th>133 (140 hips)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age at the time of surgery ± SD (min–max)</td>
<td>69 years ± 12 (35–92 years)</td>
</tr>
<tr>
<td>Body mass index mean ± SD (kg/m²) (min–max)</td>
<td>27 kg/m² ± 11 (16–39)</td>
</tr>
<tr>
<td>Sex, n, (%)</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>85 (61%)</td>
</tr>
<tr>
<td>Women</td>
<td>55 (39%)</td>
</tr>
<tr>
<td>Side</td>
<td></td>
</tr>
<tr>
<td>Right</td>
<td>84 (60%)</td>
</tr>
<tr>
<td>Left</td>
<td>56 (40%)</td>
</tr>
<tr>
<td>THA indication, n, (%)</td>
<td></td>
</tr>
<tr>
<td>Hip osteoarthritis</td>
<td>132 (94%)</td>
</tr>
<tr>
<td>Avascular necrosis</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Congenital dislocation and dysplasia</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Type of Corail™ Standard stem used, n (%)</td>
<td></td>
</tr>
<tr>
<td>Collarless (KS)</td>
<td>112 (80%)</td>
</tr>
<tr>
<td>Collared (KA)</td>
<td>28 (20%)</td>
</tr>
<tr>
<td>Size of stem used, n (%)</td>
<td></td>
</tr>
<tr>
<td>≤ 11</td>
<td>79 (56%)</td>
</tr>
<tr>
<td>&gt; 11</td>
<td>61 (44%)</td>
</tr>
</tbody>
</table>
bilateral single-stage implantation. The height of the neck cut was determined based on the preoperative plans. Increasingly larger broaches were inserted into the femoral canal until satisfactory vertical and rotational stability was achieved without needling close cortical contact. The calcar was reamed when a collared stem was used. The last broach was used as a trial stem to select the best trial neck and head length for appropriate stability and leg length. The trial implant was then replaced by the selected stem (Fig. 3).

The acetabular implant was an Allofit cup (Zimmer, Warsaw, IN) with ceramic liner and head (Metasul, Sulzer) (n = 65, 46%) or ceramic liner and head (Cerasul, Sulzer) (n = 42, 30%). The Morse taper of the Metasul and Cerasul heads (5°46') had a slightly different slope than the Corail™ stem’s taper (5°43'). However, since this difference did not lead to any prosthetic failures, it will not be discussed further. In other patients, a Lagoon cup (DePuy, Warsaw, IN) was used with a ceramic-ceramic bearing (n = 20, 14%) or a dual mobility Avantage cup (Biomet, Warsaw, IN) (n = 6, 4%), as were seven other types of cups. The acetabular component was not considered an exclusion criterion despite the large variations because the survival analysis only focused on the stem.

3.1. Assessment methods

The clinical Merle-d’Aubigné (PMA) score [6] was determined preoperatively and at the last follow-up. Postoperative complications were collected at the last follow-up.

3.2. Statistical analysis

Implant survivorship was determined using the Kaplan-Meier method with 95% confidence intervals (CI) with stem revision for aseptic loosening and stem revision or removal for any reason as the end-points. Risk factors for revision were analyzed in a univariate analysis; a multivariate analysis was performed using known risk factors and those identified as statistically significant in the univariate analysis. The statistical analysis was carried out with R software (R Core Team, Vienna, Austria). Significance threshold was set at $P < 0.05$.

4. Results

4.1. Implant survivorship and functional outcomes

Six patients underwent revision of the femoral stem (Table 2) including two cases of aseptic loosening, twoperiprosthetic joint infections and two periprosthetic fractures. The mean time to revision was 5 ± 4 years [0–11]. Stem survivorship for revision due to aseptic loosening was 98% at 12 years (95% CI: [0.96–1]) (Fig. 4). Survivorship free of stem revision or removal for any reason at 12 years was 95% (95% CI: [0.92–0.99]) (Fig. 5). For these two survivorship assessments, 40 patients had more than 12 years’ follow-up and were included in the analysis. The mean PMA score was 12 ± 2.6 [5–17] preoperatively and 16 ± 2.7 [7–18] at the last follow-up ($P < 0.0001$).

4.2. Complications and revisions

Eighteen complications were recorded at the last follow-up. There were 15 early complications:

- six dislocations between day 1 and day 30 postoperatively;
- five intraoperative calcar fractures treated by wire cerclage;
- two greater trochanter fractures treated non-surgically;
- two cases of sciatic nerve palsy (one resolved and one persistent).
Table 2
Details femoral stem revision cases.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age (years)</th>
<th>BMI (kg/m²)</th>
<th>Stem type</th>
<th>Size</th>
<th>Bearing type</th>
<th>Time elapsed before revision (years)</th>
<th>Reason for revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>77</td>
<td>24</td>
<td>KS</td>
<td>9</td>
<td>Metal-on-metal</td>
<td>0.01</td>
<td>Periprosthetic fracture</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>27</td>
<td>27</td>
<td>KA</td>
<td>11</td>
<td>Ceramic-on-ceramic</td>
<td>2</td>
<td>Infection</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>52</td>
<td>29</td>
<td>KS</td>
<td>8</td>
<td>Metal-on-metal</td>
<td>3</td>
<td>Infection</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>82</td>
<td>34</td>
<td>KS</td>
<td>11</td>
<td>Metal-on-metal</td>
<td>3.5</td>
<td>Periprosthetic fracture</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>57</td>
<td>22</td>
<td>KS</td>
<td>11</td>
<td>Metal-on-metal</td>
<td>8</td>
<td>Aseptic loosening</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>38</td>
<td>25</td>
<td>KS</td>
<td>11</td>
<td>Ceramic-on-ceramic</td>
<td>11</td>
<td>Aseptic loosening</td>
</tr>
</tbody>
</table>

F: female; M: male; KS: collarless stem; KA: collared stem.

There were 3 late complications:

- two cases of iliopsoas irritation (1 resolved by corticosteroid injection);
- one ceramic liner fracture.

Four patients had the acetabular implant revised: 1 due to liner fracture, 1 patient with iliopsoas irritation for whom corticosteroid injection was not effective and 2 of the 6 dislocation cases.

4.3. Risk factors for revision

The regression analysis showed that younger patients had a statistically higher risk of femoral stem revision (all reasons combined) ($P=0.01$) and aseptic loosening ($P=0.04$) (Table 3). Analysis by age found a significant relationship between revision for any reason and being less than 58 years of age ($P=0.02$, OR = 8.14, 95% CI [0.5–47]). Implantation of a size 11 stem or smaller was significantly associated with revision for any reason ($P=0.04$).

The multivariate analysis confirmed the significant relationship between being younger at the time of implantation and stem revision for any reason ($P=0.04$). This significant relationship was also found when the patients were analyzed by age (over or under 58 years of age) ($P=0.04$). The multivariate analysis did not confirm femoral stem size (< 11) as being a risk factor for revision (Table 3).

5. Discussion

Older models of the Corail stem have good long-term survivorship [1,2]. In our study, survival of the Corail™ standard stem free of revision for aseptic loosening was 98% at 12 years. Survival free of any revision or stem removal was 95% at 12 years. The PMA score improved significantly in this cohort from 12 to 16 at the last follow-up. This is comparable to other published studies. Out of 357 patients reviewed after 23 years of follow-up, Vidalain [1] reported that 61% of patients had a PMA score of 18 and the PMA had improved by an average of 7 points relative to the preoperative score. More recently, Gerdesmeyer et al. [7] reported an increase in the PMA from 9.5 ± 2 preoperatively to 15 ± 3 at the last
follow-up in an analysis of cementless stem with porous metallic coating at 19 years. The effect of BMI on the risk of complications after THA is well-known [8,9]. The most common complications are aseptic loosening and dislocation. Electricwala et al. [10] found a five times greater risk of aseptic loosening in patients with a BMI above 40 kg/m². These findings cannot easily be compared to French studies and the current study, given that there are fewer obese patients (the highest BMI in our study was 39 kg/m²).

The strengths of our study are the comprehensive collection of clinical data and information on complications and revisions. Nevertheless, our study has some limitations:

- its retrospective design;
- relatively small sample size (potential lack of statistical power);
- use of different acetabular cups; however, our study focused on stem survival and the type of cup was not predictive of femoral revision;
- the Corail stem was used with heads and Morse tapers from different manufacturers, which was allowed with the first-generation stem, but is not allowed now because of slight differences in the taper angles (5°46’ for Cerasul and Metasul heads vs. 5°43’ for the Corail™ stem).

There were no fractures of the ceramic head or complications that could have been related to metal corrosion in our study; however, the manufacturer specifies that the head must match the stem.

The survivorship of the current Corail™ standard stem at 12 years is satisfactory (98% without aseptic loosening and 95% without revision). These values are slightly different from the ones reported in published studies with the first- and second-generation stems. Vidalain et al. [3] and Froimson et al. [11] looked at the first-generation stem after 10 years and found survival without surgical revision of 98% and without aseptic loosening of 100%. Merini et al. [2] found no aseptic loosening after 10 years with the second-generation stem; however, the overall survival rate was 90.5% due to a high implant fracture rate (laser etching on the neck). Our study found no instances of stem fracture since the position of this marking was modified. With other types of femoral stems, a multinational study published in 2014 [12] reported 10-year survivorship of cemented stems ranging from 93.5% to 94% and that of cementless stems ranging from 91% to 93% depending on patient age – this is consistent with our data.

In our study, younger patients had a higher risk of revision. This is a known risk factor [13–15]; it can be explained by the larger stresses on the stem induced by sustained activity over a longer period. The reasons for revision in older adults are typically periprosthetic fracture or dislocation [16–18]. In our study, the two patients who suffered a periprosthetic fracture were above 75 years of age at the time of implantation. We did not find that a small-sized stem was a predictor of loosening in our study, which could be due in part to the small number of stems revised. Small stem size was proposed by Jameson et al. [5] to be a risk factor, however, this was not confirmed in larger studies [19,20].

### 6. Conclusion

This study of the first 140 consecutive Corail™ standard stems implanted at our hospital shows that this new implant has satisfactory reliability with 98% survival free of revision for aseptic loosening and 95% survival free of stem revision or stem removal at 12 years. Younger patients have a higher risk of revision for any reason. This cohort will be followed to determine whether these good results are maintained over the very long-term. The newest model of the Corail™ stem solved the prosthesis neck fracture issue without generating new complications. Its survival is similar to the first-generation stem.

### Disclosure of interest

M.H.F. receives royalties from DePuy and SERF. A.V. received scholarships from SERF and Adler Ortho unrelated to this study. L.L. and R.D. declare that they have no competing interest.

### Funding

No specific funding was received for this study.

### References